REMARKS

Support for the Amendments to the Specification

The specification has been amended to include the broader concentration range of the triglyceride component in the feed composition, that is, from about 0.05% to about 20%. Support for this amendment can be found in claim 9 as originally filed in the PCT application (WO 00/74497). No new matter is introduced.

Claim Status

Claim 1 has been amended to specify the concentrations of the triglyceride and active lipolytic enzyme components for the feed composition. The support for the concentration range of the triglyceride can be found in claim 9 as originally filed in the PCT application (WO 00/74497). The recitation of "at least one" has been deleted from the claim for clarity purpose. Support for this amendment can be found on page 6, lines 14-17 of the specification. Claim 1 has also been amended to point out non-naturally occurring differences between the claimed product and naturally occurring product by incorporating the subject matters of dependent claims 6 and 7. No new matter is introduced.

Claims 4-7 have been cancelled.

Claim 12, dependent of claim 1, has been amended to delete the subject matter that is already included in claim 1 as amended. No new matter is introduced.

Claims 15-19 have been cancelled for being non-elected claims. Applicants reserve right to file divisional applications on these claims.

Claim 20 has been amended to correct a dependency error as well as to clarify the intended target animals. Claim 21, dependent of claim 20, has also been amended for clarity purpose. No new matter is introduced.

Claims 22-25 have been added. Support for these new claims can be found in Table 1, on page 10 and Table 10, on page 22 of the PCT publication (WO 00/74497). No new matter is introduced.

With these amendments, there are now 15 claims pending, namely claims 1-3, 8-12, 14 and 20-25.

Rejection under 35 U.S.C. § 101

Claims 1-5, 8, 14 and 20-21 were rejected under 35 U.S.C. § 101 as allegedly being directed to a non-statutory subject matter. In response, Applicants have amended the independent claim 1 to recite, "wherein said triglyceride is an industrially prepared triglyceride composition or is a mixture of a naturally occurring triglyceride composition and industrially prepared triglyceride composition", indicating the hand of man. This rejection is now overcome.

Rejection under 35 U.S.C. § 112

Claims 1-12, 14 and 20-21 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In response, Applicants have amended claims 1, 12, 20 and 21 and cancelled claims 5-7 to address the issues pointed out by the Examiner. Claim 4 has been cancelled as suggested by the Examiner. Regarding the term "ppm" cited in claim 1, Applicants submit that such term is repeatedly used in the specification to refer to the concentration of the

enzyme(s) and that one of ordinary skill in the art would know what the term means and how to measure the concentration of the enzyme(s) in ppm.

It is believed that the claims as amended are now definite and that the rejection under 35 U.S.C. § 112 is overcome.

Rejections under 35 U.S.C. § 102

Claims 1-5, 8-11 and 20-21 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tang *et al.* and Hurley. Applicants respectfully traverse this rejection.

Tang *et al.* discloses a dietary composition comprising a nutritional base containing fats and bile salt-activated lipase (*See* claim 1). Tang *et al.* also discloses that human skim milk contains a about 0.1 mg/ml bile salt-activated lipase (BAL) (col. 4, lines 38-39) and specifically mentions that the bile salt-activated lipases are secreted inactive and are activated in the intestines in the presence of bile salts (emphasis added, col. 1, lines 48-52). Tang *et al.* does not disclose a feed composition of a triglyceride component combined with an active lipolytic enzyme component as presently claimed (emphasis added). In fact, Tang *et al.* teaches away from the present invention by stating that when treating a disorder of absence or deficiency of bile salt production, concomitant administration of bile salts is required and that the bile salts and the enzyme should not be allowed to react with the fats prior to their ingestion as this will result in unpalatable flavor (*See* col. 5, lines 32-36). That is, the fats (triglycerides) would not be combined with the lipase until the ingestion in the case of the bile salt disorder so mentioned.

Hurley discloses that natural human or bovine milk contains 4% triglyceride (*See* the table on page 2) and that natural human milk further contains lipases (page 3, second paragraph).

Hurley does not disclose a feed composition prepared industrially that comprises about 0.25% to about 10% triglyceride and about 100 to 10,000 ppm active lipolytic enzyme as presently claimed. Additionally, Hurley is silent on C_4-C_{12} medium chain fatty acids-containing triglycerides.

Applicants submit that the feed composition prepared industrially as claimed in the present invention allows the use of specific concentrations and ratios of different medium chain fatty acids. Unlike naturally occurring triglycerides, industrially prepared triglycerides contain certain medium chain fatty acids in certain concentrations and ratios as desired to produce compositions with better therapeutic effects. *See* Table 1, page 10 of the specification. For example, industrially prepared triglycerides MCTG 1 and MCTG 2 contain much higher concentrations of C_8 and C_{10} fatty acids compared to naturally occurring butterfat and coconut oil. Based on the description as originally filed (Table 1, page 10; Table 10, page 22), Applicants have added new claims 22-25 to further differentiate the industrially prepared triglycerides from naturally occurring triglycerides.

It is believed that the high content of C_6-C_{10}, especially C_8 and C_{10} medium chain fatty acids in the industrially prepared triglycerides leads to the unexpected therapeutic effects of the feed composition as presently claimed. As further described in the specification (*See* Example 2, Tables 3 and 4, pages 12-13), MCTG 1 and MCTG 2 demonstrate a 100 to 1000-fold activity in reducing bacterial count when compared to compositions of coconut oil or butterfat combined with the lipase(s), which only show a 10-fold activity.

In view of the above remarks, Tang *et al.* and Hurley, taken alone or combined, do not teach each and every element of the present claims. Thus, this rejection should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1-12, 14 and 20-21 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.* Applicants respectfully traverse this rejection.

Hull *et al.* discloses a method of producing sweet cream buttermilk from lipolyzed cream. In detail, lipolyzed cream is prepared by first incubating cream with an enzyme preferably a lipase, then heating the cream to a temperature sufficiently high to inactivate the lipase, and lastly cooling the lypolyzed cream (*See* col. 2, line 22 – col. 3, line 10). It is believed that Hull's composition contains no active lipolytic enzymes.

Haas *et al.* discloses a palatability improving composition comprising fat and protein which has been conditioned by emulsifying the fat and treating the mixture with lipase and protease (*See* Abstract). Hass *et al.* further discloses that the emulsion is then subjected to an enzyme inactivation step (*See* col. 3, lines 63-68). It is also believed that Hass's composition contains no active lipolytic enzymes. Additionally, Haas *et al.* further teaches away from the present invention by stating that the concentration of the lipase is not considered critical (*See* col. 2, line 65 – col. 3, line 4).

Contrarily to Hull *et al.* and/or Haas *et al.*, the present feed composition when administered to early weaned animals provides said animals with active lipolytic enzymes and helps to overcome the pronounced deficiency of lipolytic enzymes observed in these animals shortly after weaning (*See* specification, page 7, lines 29-32).

As discussed above, Tang *et al.* does not disclose a feed composition of a triglyceride component combined with an active lipolytic enzyme component as presently claimed.

There are no teachings or suggestions in the above references with respect to the presently claimed composition as well as its surprising therapeutic properties. None of the references teaches or suggests the use of an active lipolytic enzyme for their compositions prior to being digested in the intestines of the animals (emphasis added).

The objective problem addressed by the present invention is how to provide a feed composition that alleviates and/or prevents health problems encountered by animals in their early growth, for example when early weaned. The present invention solves this problem by providing a feed composition comprising a triglyceride component and a lipolytic enzyme component, wherein the triglyceride component contains medium chain fatty acids (MCFA) and is an industrial triglyceride composition or is a mixture of naturally occurring triglycerides and industrially prepared triglycerides. The surprising therapeutic properties of industrial MCFA-containing triglycerides in combination with a lipolytic enzyme component are clearly demonstrated in the present application (*See* Example 2, Tables 3 and 4, pages 12-13). Such combination composition shows surprisingly a 100 to 1000-fold activity in reducing bacterial count when compared to compositions of coconut oil or butterfat combined with the lipase(s), which only show a 10-fold activity. The use of such composition further prevents digestive upsets and moreover has a positive effect on growth without negative side effects (*See* page 8, lines 7-16). These surprising properties are due to the combined effect of the industrially prepared MCFA triglycerides and the lipolytic enzyme component in the composition. The gradual lipolysis of the triglycerides by the enzyme results in the release of medium chain fatty

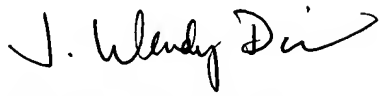
acids in the stomach, which have a sterilizing effect thereby providing the therapeutic effects cited above.

The presently claimed composition unexpectedly provides a physiological environment in the stomach of early-weaned animals that regulates and stabilizes gastrointestinal flora. Such composition has unexpectedly high bacteriostatic and bactericidal activity against Gram-positive and Gram negative bacteria (*See*, Experiment 4, Table 9). The specified concentration of active lipolytic enzymes in the present composition is beneficial to help overcome the pronounced deficiency of lipolytic enzymes in such animals shortly after weaning.

In view of the above remarks, neither the feed composition presently claimed, nor the above-mentioned unexpected benefits provided by such compositions, would have been apparent from Hull *et al.*, Haas *et al.*, and Tang *et al.* Hull, alone or combined. Therefore, Hull *et al.* taken with Haas *et al.* and Tang *et al.* would not have rendered obvious the present invention as claimed. Applicants respectfully request that the rejection under 35 U.S.C. 103 be withdrawn.

This document is being filed along with a petition for two-month extension of time. The Commissioner is authorized to deduct the extension fee ($450) from Deposit Account No. 01-2508/13475.0003.PCUS00. Should any other fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is authorized to deduct said fees from the same Deposit Account.

Respectfully submitted,



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